

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION: James A. O'SHELL, JR.

GROUP ART U. Unassigned

SERIAL NUMBER: 10/549,804

EXAMINER: Unassigned

FILED: September 19, 2005

FOR: PLASMINOGEN ACTIVATOR INHIBITOR-1 (PAI-1) HAPLOTYPES USEFUL AS INDICATORS OF PATIENT OUTCOME

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. 1.97

Mail Stop Amendment
 Commissioner for Patents
 P.O. Box 1450
 Alexandria, VA 22313-1450

Sir:

Applicant(s) wish to disclose the following information.

REFERENCES

- ☒ The Applicant(s) wish to make of record the references listed on the attached PTO/ SB/08. Copies of the listed references are attached, where required, as are either statements of relevancy or any readily available English translations of pertinent portions of any non-English language references.
- ☐ A check is attached in the amount required under 37 CFR § 1.17(p).

RELATED CASES

- ☐ Attached is a list of applicant's pending applications or issued patents which may be related to the present application. A copy of the patent(s) is attached along with PTO/ SB/08.
- ☐ A check is attached in the amount required under 37 CFR § 1.17(p).

CERTIFICATION

The undersigned certifies that

- ☐ each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement.
- ☐ no item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned, having made reasonable inquiry, was known to any individual designated in 37 CFR § 1.56(c) more than three months prior to the filing of this statement.

PETITION

- ☐ Applicant(s) hereby request consideration of the attached information. A check is attached in the amount of the Petition fee required under 37 CFR § 1.17(i)(1).

DEPOSIT ACCOUNT

- ☒ Please charge any additional fees for the papers being filed herewith and for which no check is enclosed herewith, or credit any overpayment to deposit account No. 50-0911. A duplicate copy of this sheet is enclosed.

Respectfully submitted,
 MCKENNA LONG & ALDRIDGE LLP

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1

of 2

Complete if Known

Application Number 49,804

Filing Date September 19, 2005

First Named Inventor WALLEY, Keith R.

Art Unit TBA

Examiner Name TBA Pohnert

Attorney Docket Number 28903.0003 (SBF-3)

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
/SP/	A1	US 5,128,247				
	A2	US 5,130,423				
	A3	US 5,674,743				
	A4	US 5,945,515				
	A5	US 5,989,431				
	A6	US 6,025,136				
	A7	US 6,270,961				

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ³
		Country Code ³	Number ⁴	Kind Code ⁵ (if known)				
/SP/	B1	WO	01/81631					
/SP/	B2	WO	98/53098					

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Document Cited ¹	T ²
/SP/	C1	American College of Chest Physicians/Society of Critical Care Medicine Consensus Conference: definitions for sepsis and organ failure and guidelines for the use of innovative therapies in sepsis (Critical Care Medicine (1992) 20(6):864-874.	
↓	C2	Analects, (1994) Vol. 22, No. 4 Pharmacia Biotech.	
	C3	Anonymous, Ventilation with lower tidal volumes as compared with traditional tidal volumes for acute lung injury and the acute respiratory distress syndrome. New England Journal of Medicine (2000) 342(18):1301-8.	
	C4	Anvari, A., et al. PAI-1 4G/5G polymorphism and sudden cardiac death in patients with coronary artery disease. Thrombosis Research (2001) 103(2):103-7.	
	C5	Axelrod, V.D., et al. Specific terminal of RNA polymerase synthesis as a method of RNA and DNA sequencing. Nuc/Acids Res (1978) 5(p): 3549-3563	

Examiner Signature	/Steven Pohnert/ (08/27/2009)	Date Considered	
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DC:50377013.1

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 2 of 3

Complete If Known

Application Number 549,804

Filing Date September 19, 2005

First Named Inventor WALLEY, Keith R.

Art Unit TBA

Examiner Name TBA Pöhner

Attorney Docket Number 28903.0003 (SBF-3)

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS (...cont.)

Examiner Initials *	Cite No. ¹	Document Cited	T
/SPI	C6	Benza, Raymond L. "Association of a gene polymorphism for PAI-1 with primary pulmonary hypertension" American Heart Association Cardiopulmonary and Critical Care Council Newsletter, 23(1), Spring 2002, p. 7-8.	
	C7	Bernard, G.R., et al. The effects of ibuprofen on the physiology and survival of patients with sepsis. New England Journal of Medicine (1997) 336(13):912-8.	
	C8	Bernard, G.R., et al. Efficacy and safety of recombinant human activated protein c for severe sepsis. New England Journal of Medicine (2001) 344(10):699-709.	
	C9	Binder, B.R., et al. Plasminogen activator inhibitor 1: physiological and pathophysiological roles. News in Physiological Sciences (2002) 17:56-61.	
	C10	Boekholdt, S.M., et al. Genetic variation in coagulation and fibrinolytic proteins and their relation with acute myocardial infarction. Circulation (2001) 104(25):3063-8.	
	C11	Catchpole, DR, Lock, RB. "The potential tumour suppressor role for caspase-9 (CASP9) in the childhood malignancy, neuroblastoma", Eur J Cancer (2001) 37(17):2217-21.	
	C12	Dawson, S.J., et al. The two allele sequences of a common polymorphism in the promoter of the plasminogen activator inhibitor-1 (PAI-1) gene respond differently to interleukin-1 in HepG2 cells. Journal of Biological Chemistry (1993) 268(15):10739-45.	
	C13	Dawson, S., et al. Genetic variation at the plasminogen activator inhibitor-1 locus is associated with altered levels of plasma plasminogen activator inhibitor-1 activity. Arteriosclerosis & Thrombosis (1991) 11(1):183-90.	
	C14	Endler, G., et al. The 4G/5G genotype at nucleotide position -675 in the promoter region of the plasminogen activator inhibitor 1 (PAI-1) gene is less frequent in young patients with minor stroke than in controls. British Journal of Haematology (2000) 110(2):469-71.	
	C15	Erkkonen, P., et al. Allele-specific increase in basal transcription of the plasminogen-activator inhibitor 1 gene is associated with myocardial infarction. PNAS (1999) 92(6): 1851-5.	
	C16	Fournier, F., et al. Septic shock, multiple organ failure, and disseminated intravascular coagulation: compared patterns of antithrombin III, protein c, and protein s deficiencies. Chest (1992) 101(3):816-23.	
	C17	Freeman, B.D., et al. Template-directed dye-terminator incorporation with fluorescence polarization detection for analysis of single nucleotide polymorphisms implicated in sepsis. J Mol Diagnostics (2002) 4(4):209-215.	
	C18	Gaillard, MC, Mahadeva, R., Lomas DA. "Identification of DNA polymorphisms associated with the V type alpha1-antitrypsin gene", Biochim Biophys Acta (1999) 1444(29):166-70.	
	C19	Gardemann, A., et al. The 4G/5G genotype of the plasminogen activator inhibitor 4G/5G gene polymorphism is associated with coronary atherosclerosis in patients at high risk for this disease. Thrombosis & Haemostasis (1999) 82(3):1121-6.	
	C20	Harelambous, E., et al. Role of functional plasminogen-activator-inhibitor-1 4G/5G promoter polymorphism in susceptibility, severity, and outcome of meningococcal disease in caucasian children. Crit Care Med (2003) 31(12):2788-93.	
	C21	Hermans, P.W., et al. 4G/5G promoter polymorphism in the plasminogen-activator-inhibitor-1 gene and outcome of meningococcal disease. Lancet (1999) 354(9178):556-60.	
	C22	Hesselvik, J.F., et al. Coagulation, fibrinolysis, and kallikrein systems in sepsis: relation to outcome. Critical Care Medicine (1989) 17(6):724-33.	
	C23	Hindorf, L.A., et al. The association of PAI-1 promoter RG/5G insertion/deletion polymorphism with myocardial infarction and stroke in young women. Journal of Cardiovascular Risk (2002) 9(2):131-7.	
	C24	Hooper, W.C., et al. The role of the t-Pa I/D and PAI-1 4G/5G polymorphisms in african-american adults with a diagnosis of myocardial infarction or venous thromboembolism. Thrombosis Research (2000) 99(3):223-30.	
	C25	Johnson, K., et al. Potential mechanisms for a proinflammatory vascular cytokine response to coagulation activation. Journal of Immunology (1998) 160(10):5130-5.	
	C26	Johnson, K., et al. The proinflammatory cytokine response to coagulation and endotoxin in whole blood. Blood (1996) 87(12):5051-60.	

Examiner
Signature

/Steven Pöhner/ (08/27/2005)

Date

Considered

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet 3 of 3

Application Number	549,804
Filing Date	September 19, 2005
First Named Inventor	WALLEY, Keith RIAN 2, 4 2005
Art Unit	TBA
Examiner Name	TBA
Attorney Docket Number	28903.0003 (SBF-3)

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS (...cont.)

Examiner Initials *	Cite No. ¹	Document Cited	T
/SP	C27	Jones, K., et al. The influence of 4G/5G polymorphism in the plasminogen activator inhibitor-1 gene promoter on the incidence, growth and operative risk of abdominal aortic aneurysm. European Journal of Vascular & Endovascular Surgery (2002) 23(5):421-5.	
	C28	Lopez-Aguirre, Y., et al. Endothelial cell and hemostatic activation in relation to cytokines in patients with sepsis. Thrombosis Research (1999) 94(2):95-101.	
	C29	Lorente, J.A., et al. Time course of hemostatic abnormalities in sepsis and its relation to outcome. Chest (1993) 103(5):1536-42.	
	C30	Menges, T., et al. Plasminogen-activator-inhibitor-1 4G/5G promoter polymorphism and prognosis of severely injured patients. Lancet (2001) 357(9262):1096-7.	
	C31	Mesters, R.M., et al. Factor VIIa and antithrombin III activity during severe sepsis and septic shock in neutropenic patients. Blood (1996) 88(3):881-6.	
	C32	Mesters, R.M., et al. Increase of plasminogen activator inhibitor levels predicts outcome of leukocytopenic patients with sepsis. Thrombosis & Haemostasis (1996) 75(6):902-7.	
	C33	Mikkelsen, J., et al. Plasminogen activator inhibitor-1 (PAI-1) 4G/5G polymorphism coronary thrombosis, and myocardial infarction in middle-aged Finnish men who died suddenly. Thrombosis & Haemostasis (2000) 84(1):78-82.	
	C34	Noguchi, E., et al. "Identification of missense mutation in the IL12B gene: lack of association between IL12B polymorphisms and asthma and allergic rhinitis in the Japanese population", Genes Immun (2001) 2(7):401-3.	
	C35	Ortlepp, J.R., et al. The 4G/5G promoter polymorphism of the plasminogen activator inhibitor-1 gene and late lumen loss after coronary stent placement in smoking and nonsmoking patients. Clinical Cardiology (2001) 24(9):585-91.	
	C36	Phillips, J., et al. Fibrinolysis and coagulation in patients with infectious disease and sepsis. Thromb Haemost (1991) 65(3):291-5.	
	C37	Pralong, G., et al. Plasminogen activator inhibitor 1: a new prognostic marker in septic shock. Thromb Haemost(1989) 61(3):459-62.	
	C38	Rieder, M.J., et al. Accession AF366492 Vol. 2001: Seattle SNPs. NHLBI Program for Genomic Applications, UW-PHCRC, Seattle, WA (2001).	
	C39	Roest, M., et al. Plasminogen activator inhibitor 4G polymorphism is associated with decreased risk of cerebrovascular mortality in older women. Circulation (2000) 101(1):67-70.	
	C40	Russell, J.A. Genetics of Coagulation factors in acute lung injury. Critical Care Medicine (2003) 31(4):S243-S24.	
	C41	Russell, J.A., et al. Changing pattern of organ dysfunction in early human sepsis is related to mortality. Critical Care Medicine (2000) 28(10):3405-11.	
	C42	Segui, R., et al. PAI-1 promoter 4G/5G genotype as an additional risk factor for venous thrombosis in subjects with genetic thrombophilic defects. British Journal of Haematology (2000) 111(1):122-8.	
	C43	Suffredini, A.F., et al. Promotion and subsequent inhibition of plasminogen activation after administration of intravenous endotoxin to normal subjects. New England Journal of Medicine (1989) 320(18):1165-72.	
	C44	Tabrizi, A.R., et al. Genetic markers in sepsis. J Am Coll Surg (2001) 192(1):108-117.	
	C45	Vincent, et al. Scoring systems for assessing organ dysfunction and survival. Critical Care Clinics (2000) 16:353-366.	
✓	C46	Westendorp, R.G., et al. Variation in plasminogen-activator-inhibitor-1 gene and risk of meningococcal septic shock. Lancet (1999) 354(9178):561-3.	

Examiner Signature	/Steven Pohnert/ (08/27/2009)
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Date Considered	
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